

Enramycin Formulation

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| Version | Revision Date: | SDS Number: | Date of last issue: 20.03.2023 |
| 3.1 | 26.09.2023 | 24567-00021 | Date of first issue: 22.10.2014 |

SECTION 1. IDENTIFICATION

Product name : Enramycin Formulation

Manufacturer or supplier's details

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma
Buenos Aires, Argentina C1013AAP

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 2

GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H400 Very toxic to aquatic life.
H411 Toxic to aquatic life with long lasting effects.

Precautionary Statements : **Prevention:**
P273 Avoid release to the environment.
Response:
P391 Collect spillage.
Disposal:
P501 Dispose of contents/ container to an approved waste

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disposal plant.

Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosible dust-air mixture if dispersed.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|---------------|------------|------------------------|
| Talc | 14807-96-6 | ≥ 90 - ≤ 100 |
| ENRAMYCIN B | 34304-21-7 | ≥ 5 - < 10 |

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention if symptoms occur.

In case of skin contact : Wash with water and soap.
Get medical attention if symptoms occur.

In case of eye contact : If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

Protection of first-aiders : No special precautions are necessary for first aid responders.

Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : High volume water jet

Specific hazards during fire fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Do not use a solid water stream as it may scatter and spread fire.
Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- : Carbon oxides

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| ucts | Nitrogen oxides (NO _x) |
| Specific extinguishing methods | : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area. |
| Special protective equipment for fire-fighters | : Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment. |

SECTION 6. ACCIDENTAL RELEASE MEASURES

| | |
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| Personal precautions, protective equipment and emergency procedures | : Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
| Environmental precautions | : Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained. |
| Methods and materials for containment and cleaning up | : Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. |

SECTION 7. HANDLING AND STORAGE

| | |
|-------------------------|---|
| Technical measures | : Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. |
| Local/Total ventilation | : Use only with adequate ventilation. |
| Advice on safe handling | : Do not breathe dust. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take care to prevent spills, waste and minimize release to the environment. |

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Conditions for safe storage : Keep in properly labeled containers.
 Store in accordance with the particular national regulations.
 Materials to avoid : No special restrictions on storage with other products.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|-------------|------------|-------------------------------------|--|----------|
| Talc | 14807-96-6 | CMP (Respirable fraction) | 2 mg/m ³ | AR OEL |
| | | TWA (Respirable particulate matter) | 2 mg/m ³ | ACGIH |
| ENRAMYCIN B | 34304-21-7 | TWA | 5 mg/m ³ (OEB 1) | Internal |

Engineering measures : Use feasible engineering controls to minimize exposure to compound.
 All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection : Chemical-resistant gloves

Material : Chemical-resistant gloves

Eye protection : Wear safety glasses with side shields or goggles.
 If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
 Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
 When using do not eat, drink or smoke.
 Wash contaminated clothing before re-use.
 The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

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| | | |
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| Appearance | : | powder |
| Color | : | light brown |
| Odor | : | characteristic |
| Odor Threshold | : | No data available |
| pH | : | 5 - 8,5 |
| Melting point/freezing point | : | No data available |
| Initial boiling point and boiling range | : | No data available |
| Flash point | : | No data available |
| Evaporation rate | : | No data available |
| Flammability (solid, gas) | : | No data available |
| Flammability (liquids) | : | No data available |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Vapor pressure | : | No data available |
| Relative vapor density | : | No data available |
| Relative density | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | practically insoluble |
| Partition coefficient: n-octanol/water | : | No data available |
| Autoignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| Viscosity | | |
| Viscosity, kinematic | : | No data available |
| Explosive properties | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Molecular weight | : | No data available |
| Particle size | : | No data available |

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SECTION 10. STABILITY AND REACTIVITY

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|------------------------------------|---|--|
| Reactivity | : | Not classified as a reactivity hazard. |
| Chemical stability | : | Stable under normal conditions. |
| Possibility of hazardous reactions | : | Dust can form an explosive mixture in air. |
| Conditions to avoid | : | Avoid dust formation. |
| Incompatible materials | : | None. |
| Hazardous decomposition products | : | No hazardous decomposition products are known. |

SECTION 11. TOXICOLOGICAL INFORMATION

| | | |
|--|---|--|
| Information on likely routes of exposure | : | Inhalation Skin contact Ingestion Eye contact |
|--|---|--|

Acute toxicity

Not classified based on available information.

Components:**Talc:**

| | | |
|---|---|---------------------------|
| Acute oral toxicity | : | LD50 (Rat): > 5.000 mg/kg |
| Remarks: Based on data from similar materials | | |

ENRAMYCIN B:

| | | |
|---------------------|---|-----------------------------|
| Acute oral toxicity | : | LD50 (Mouse): > 5.000 mg/kg |
| | | LD50 (Rat): > 10.000 mg/kg |

Skin corrosion/irritation

Not classified based on available information.

Components:**Talc:**

| | | |
|---------|---|--------------------|
| Species | : | Rabbit |
| Result | : | No skin irritation |

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Talc:**

| | | |
|---------|---|-------------------|
| Species | : | Rabbit |
| Result | : | No eye irritation |

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ENRAMYCIN B:

| | | |
|---------|---|-------------------|
| Species | : | Rabbit |
| Result | : | No eye irritation |

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:**Talc:**

| | | |
|--------------------|---|--------------|
| Routes of exposure | : | Skin contact |
| Species | : | Humans |
| Result | : | negative |

Germ cell mutagenicity

Not classified based on available information.

Components:**Talc:**

| | | |
|-----------------------|---|--|
| Genotoxicity in vitro | : | Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Result: negative |
| Genotoxicity in vivo | : | Test Type: Chromosome aberration test in vitro Species: Rat Application Route: Ingestion Result: negative |

ENRAMYCIN B:

| | | |
|-----------------------|---|--|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES) Result: negative |
|-----------------------|---|--|

Carcinogenicity

Not classified based on available information.

Components:**Talc:**

| | | |
|-------------------|---|-----------------------------|
| Species | : | Mouse |
| Application Route | : | inhalation (dust/mist/fume) |
| Exposure time | : | 2 Years |
| Result | : | negative |

Reproductive toxicity

Not classified based on available information.

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Components:**Talc:**

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Repeated dose toxicity**Components:****ENRAMYCIN B:**

Species : Rat
NOAEL : 1.000 mg/kg
Application Route : Ingestion
Exposure time : 6 Months

Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Talc:**

Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)): > 100.000 mg/l
Exposure time: 24 h

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Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 1 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: No toxicity at the limit of solubility.

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 1 mg/l
aquatic invertebrates : Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: No toxicity at the limit of solubility.

Toxicity to algae/aquatic : EC50 (Pseudokirchneriella subcapitata (green algae)): 18 mg/l
plants : Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0,96

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mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

EC50 (Anabaena flos-aquae (cyanobacterium)): 0,083 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae (cyanobacterium)): 0,045 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 10
M-Factor (Chronic aquatic toxicity) : 1
Toxicity to microorganisms : EC50: 438,5 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

EC10: 0,045 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

Persistence and degradability**Components:****ENRAMYCIN B:**

Biodegradability : Result: Not readily biodegradable.
Method: OECD Test Guideline 301B

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Do not dispose of waste into sewer.
Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION**International Regulations**

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UNRTDG

| | |
|---------------------------|--|
| UN number | : UN 3077 |
| Proper shipping name | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (ENRAMYCIN B) |
| Class | : 9 |
| Packing group | : III |
| Labels | : 9 |
| Environmentally hazardous | : yes |

IATA-DGR

| | |
|--|--|
| UN/ID No. | : UN 3077 |
| Proper shipping name | : Environmentally hazardous substance, solid, n.o.s. (ENRAMYCIN B) |
| Class | : 9 |
| Packing group | : III |
| Labels | : Miscellaneous |
| Packing instruction (cargo aircraft) | : 956 |
| Packing instruction (passenger aircraft) | : 956 |
| Environmentally hazardous | : yes |

IMDG-Code

| | |
|----------------------|--|
| UN number | : UN 3077 |
| Proper shipping name | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (ENRAMYCIN B) |
| Class | : 9 |
| Packing group | : III |
| Labels | : 9 |
| EmS Code | : F-A, S-F |
| Marine pollutant | : yes |

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

| | |
|---|------------------|
| Argentina. Carcinogenic Substances and Agents Registry. | : Not applicable |
|---|------------------|

| | |
|---|------------------|
| Control of precursors and essential chemicals for the preparation of drugs. | : Not applicable |
|---|------------------|

The ingredients of this product are reported in the following inventories:

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|-------|---|----------------|
| AICS | : | not determined |
| DSL | : | not determined |
| IECSC | : | not determined |

SECTION 16. OTHER INFORMATION

| | | |
|---------------|---|------------|
| Revision Date | : | 26.09.2023 |
| Date format | : | dd.mm.yyyy |

Further information

| | | |
|--|---|---|
| Sources of key data used to compile the Material Safety Data Sheet | : | Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/ |
|--|---|---|

Full text of other abbreviations

| | | |
|--------------|---|---|
| ACGIH | : | USA. ACGIH Threshold Limit Values (TLV) |
| AR OEL | : | Argentina. Occupational Exposure Limits |
| ACGIH / TWA | : | 8-hour, time-weighted average |
| AR OEL / CMP | : | TLV (Threshold Limit Value) |

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

AR / Z8